

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and  
EDWARDS LIFESCIENCES LLC,

Plaintiffs,

v.

C.A. No. 08-91 (GMS)

COREVALVE, INC.,

Defendants.

REDACTED  
PUBLIC VERSION

**FINAL PRETRIAL ORDER**

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January 26, 2010 - Original Filing Date

February 2, 2010 - Redacted Filing Date

This matter having come before the Court at a Pretrial Conference held pursuant to Fed. R. Civ. P. (“Rule”) 16, and Morris, Nichols, Arsh & Tunnell LLP, 1201 North Market Street, Wilmington, Delaware 19899, (302) 658-9200 and Paul, Weiss, Rifkind, Wharton & Garrison LLP, 1285 Avenue of the Americas, New York, New York, 10019, (212) 373-3000 having appeared as counsel for plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC, and Young Conaway Stargatt & Taylor, LLP, 1000 West Street, Wilmington, Delaware 19801 (302) 571-6600 and Richards, Layton & Finger, P.A., One Rodney Square, 920 North King St., Wilmington, Delaware 19899, (302) 651-7700 and Keker & Van Nest, LLP, 710 Sansome St., San Francisco, California 94111 (415) 391-5400 having appeared as counsel for defendant CoreValve, Inc., the following actions were taken:

- (1) This action is for patent infringement by Edwards Lifesciences AG and Edwards Lifesciences LLC against CoreValve, Inc.<sup>1</sup>, including a claim for willful infringement. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338. Subject matter jurisdiction is not disputed. In the event that liability is found on U.S. Patent No. 5,411,552 and/or U.S. Patent No. 6,582,462, Edwards will seek treble damages, attorneys’ fees, and a permanent injunction. In the event that the ‘552 and/or ‘462 patents are found to be invalid or not infringed and this case is shown to be exceptional, CoreValve will seek its attorney fees under 35 U.S.C. § 285.
- (2) Edwards’ statement: On January 25, 2009, the day before the Pretrial Order papers are due, CoreValve indicated for the first time that it plans to drop its safe harbor defense. This lack of notice prevents Edwards from conforming numerous portions of this Final

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<sup>1</sup> Pending is Edwards’ motion to join CoreValve’s successors Medtronic CoreValve, LLC and Medtronic, Inc. as defendants (D.I. 167).

Pretrial Order to CoreValve's new theory. Edwards intends to meet and confer with CoreValve to resolve the matter, and file updated papers as needed.

- (3) CoreValve's statement: CoreValve did not add a "new theory" as Edwards' alleges. Rather, consistent with the local rules of this Court, CoreValve properly narrowed the issues for trial by electing not to pursue its affirmative defense based on the safe harbor provision of 35 U.S.C. § 271(e). CoreValve is unaware how a narrowing of its affirmative defenses could affect Edwards' contentions, or prevent Edwards from presenting those issues in this Final Pretrial Order.
- (4) The following stipulations and statements were submitted and are attached to and made a part of this Order.
  - (a) a comprehensive stipulation or statement of all uncontested facts, which will become a part of the evidentiary record in the case and which may be read to the jury by the court or any party (**Exhibit A**);
  - (b) an agreed statement of the contested issues of fact and law and a statement or statements of contested issues of fact or law not agreed to (**Exhibit B**);
  - (c) except for rebuttal exhibits, impeachment exhibits and demonstrative exhibits, schedules of all exhibits, including documents, summaries, charts and other items expected to be offered in evidence;
    - (1) for Edwards (**Exhibit C**); and
    - (2) for CoreValve (**Exhibit D**).

(3) Demonstrative exhibits are not included on these lists; the parties have agreed to the following dates to exchange copies of demonstrative exhibits (in color if applicable):

March 16, 2010	Exchange of demonstrative exhibits to be used in opening statements to the jury
March 19, 2010	Exchange of demonstratives other than for opening statements or closing arguments to the jury
No later than 5:00 PM Day Prior To Closing Arguments	Exchange of demonstrative exhibits to be used in closing arguments

The parties further agree to meet and confer regarding any demonstrative in an effort to resolve any possible disputes or objections regarding the demonstrative prior to its expected use in Court.

(d) The descriptions of the exhibits on the parties' respective exhibit lists are for identification purposes only and the parties are not agreeing that the descriptions accurately characterize the documents. The descriptions are not admissions as to the content, admissibility or relevance of the documents. The parties reserve the right to offer exhibits that are not set forth on their exhibit lists for purposes of unanticipated rebuttal or impeachment. The parties reserve the right to offer exhibits listed on the opposing party's exhibit list. The parties have further agreed to cooperate to further refine their respective exhibit lists and objections thereto prior to trial.

- (e) a list of names and addresses of the potential witnesses to be called by each party, with a statement of any objections to calling, or to the qualifications of, any witness identified on the list:<sup>2</sup>
  - (1) for Edwards (**Exhibit E**); and
  - (2) for CoreValve (**Exhibit F**).
- (f) statements setting forth the qualifications of each expert witness in such form that the statement can be read to the jury at the time the expert witness takes the stand, and any objections thereto:
  - (1) for Edwards (**Exhibit G**); and
  - (2) for CoreValve (**Exhibit H**).
- (g) a list of all depositions, or portions thereof, to be read into evidence and objections thereto, counter-designations and objections thereto:
  - (1) for Edwards (**Exhibit I**); and
  - (2) for CoreValve (**Exhibit J**).
- (h) an itemized statement of special damages (**Exhibit K**);

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<sup>2</sup> The parties agree that notice will be given 24 hours in advance of testimony as to the names of the witnesses to be called the following day, and the order of presentation of any such witnesses.

The parties have agreed that trial depositions may be conducted of any trial witnesses not previously deposed in the case. To that end, CoreValve has agreed to notify Edwards by March 5, 2010 as to whether it will call any such witnesses, so that Edwards may take depositions as needed.

- (i) waivers of any claims or defenses that have been abandoned by any party (**Exhibit L**);
- (j) for the jury trial:
  - (1) trial briefs (Edwards' brief attached at **Exhibit M**; CoreValve's brief attached at **Exhibit N**);
  - (2) three sets of marked proposed jury instructions (**Exhibit O**)<sup>3</sup>, verdict forms (Edwards' proposed Verdict Form attached at **Exhibits P**; CoreValve's proposed Verdict Form attached at **Exhibit Q**);
  - (3) a list of the questions the parties request the Court to ask prospective jurors in accordance with Fed. R. Civ. P. 47(a) and D. Del. LR 47.1(a) (Edwards' Proposed *Voir Dire* attached at **Exhibit R**; CoreValve's Proposed *Voir Dire* attached at **Exhibit S**).
- (k) A statement summarizing the history and status of settlement negotiations, indicating whether further negotiations are ongoing and likely to be productive (**Exhibit T**);
- (l) A statement as to whether each party has completed discovery, including the depositions of expert witnesses (**Exhibit U**); and

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<sup>3</sup> The parties are continuing to confer with respect to jury instructions in an effort to narrow the number of disputed instructions. The set of jury instructions included in Exhibit O reflects the parties' current respective proposals. The parties will confer and submit a revised set of instructions before trial narrowing the disputes. Objections and argument in support of each party's proposed instructions will be included in that submission.

(m) Motions *in limine*. Motions *in limine* have been briefed and are being filed contemporaneously with this document. The motions are as follows:

For Edwards:

- (1) Plaintiffs' Motion *In Limine* to Exclude All Deposition and Trial Testimony of Experts Martin Rothman and Leonard Pinchuk for Failure to Abide by the Court's *Markman* Order;
- (2) Plaintiffs' Motion *In Limine* to Exclude Evidence, Testimony, or Argument Regarding the Result of Proceedings Between the Parties in Germany and the United Kingdom;<sup>4</sup>
- (3) Plaintiffs' unopposed Motion *In Limine* to Exclude Evidence, Testimony, or Argument Regarding Patent Term Extension Law Generally or as Possibly Applied to Any of the Patents-In-Suit;
- (4) Plaintiffs' Motion *In Limine* to Preclude CoreValve, Inc. From Presenting Evidence, Testimony, or Argument to the Jury that is Related Only to Injunctive Relief and Other Issues Reserved for the Court;
- (5) Plaintiffs' Motion *In Limine* to Exclude Expert Elisa Harvey From Testifying About Third Party "SSED" Documents.<sup>5</sup>

For CoreValve:

- (1) CoreValve's Motion *In Limine* No. 1 to Exclude Evidence and Argument Regarding the Doctrine of Equivalents;
- (2) CoreValve's Motion *In Limine* No. 2 to Exclude Expert Testimony From Dr. Nigel Buller;
- (3) CoreValve's Motion *In Limine* No. 3 to Exclude Testimony and Opinions of Gregory Leonard;
- (4) CoreValve's Motion *In Limine* No. 4 to Exclude Testimony and Opinions of Gregory Leonard Criticizing Opinions of Jeffrey Kinrich.

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<sup>4</sup> CoreValve has proposed a stipulation that, if agreed to by the parties, would render this motion moot. The parties have agreed to confer with respect to this issue prior to the Pretrial Conference. Should the parties not reach an agreement, any ruling should apply equally to both parties.

<sup>5</sup> CoreValve believes this motion is moot in light of its withdrawal of the safe harbor defense. Edwards disagrees. *See* Edwards' Reply to this Motion *in Limine*.

(5) Trial of this case is expected to take 8 days.

(6) Indicate the type of trial by placing an X in the appropriate box:

Jury  <sup>6</sup> Non-Jury

(7) The parties recommend that 8 jurors be selected at the commencement of the trial and

that all 8 jurors deliberate.

(8) This Order will control the course of the trial and may not be amended except by consent  
of the parties and the Court, or by order of the Court to prevent manifest injustice.

(9) Possibility of settlement of this case was considered by the parties.

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United States District Judge

Date: \_\_\_\_\_

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<sup>6</sup> Should liability be found, Edwards will seek a hearing on Edwards' request for a permanent injunction and treble damages.

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January 26, 2010

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 2, 2010 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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RICHARDS, LAYTON & FINGER, P.A.

John W. Shaw, Esquire  
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I further certify that I caused copies of the foregoing document to be served on February 2, 2010 upon the following in the manner indicated:

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